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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,480	07/31/2006	Marc Gerspacher	33587-US-PCT	5896

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NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.
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CAMBRIDGE, MA 02139

EXAMINER

BASQUILL, SEAN M

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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02/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,480	Applicant(s) GERSPACHER ET AL.	
	Examiner Sean Basquill	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10 Jul 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Claims 1-7 directed to benzimidazole derivatives in the reply filed on October 29, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 11 has been cancelled, and Claims 8-10 have been withdrawn as directed to a nonelected invention. The examiner additionally acknowledges Applicants' election of 4-bromo-2-(4-isopropyl-phenyl)-7-methoxy-1-(2-methoxy-ethyl)-5-(3-methoxy-phenyl)-1H-benzimidazole as a species representative of the compounds of Formula I claimed in the instant application. Claims 1-7 are presented for examination.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more 119(b) as follows:

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on 14 January 2004. It is noted, however, that applicant has not filed a certified copy of the Foreign application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112 First Paragraph

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement of the first paragraph of 35 USC 112 requires that the specification contain a written description of *the invention*. Accordingly, where a particular compound has not been *specifically* named or “otherwise exemplified,” one is left to select from mere *possibilities* encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made. *In re Ruschig*, 154 USPQ 118, 122 (CCPA 1967). As elaborated by the court:

Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that *naming* is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required. Surely, given time, a chemist could name (especially with the aid of a computer) all of the half million compounds within the scope of the broadest claim, which claim is supported by the broad disclosure. This does not constitute support for each compound individually when separately claimed. (*Id.*)

Here, the instant claims broadly recite compounds with a variety of variable substituents, specifically those described in Claim 1 as R1, R2, R3, R5, and R6, and those of Claim 2 described as R'1, R'3, R'5, and R'6. The substituents of Claim 1 giving rise to the instant written description rejection are nominally identified by terms such as “optionally substituted ...lower alkenyl and lower alkynyl” for substituent R1, “optionally substituted...aryl, heteroaryl,

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aryl-lower alkyl and heteroaryl-lower alkyl” for substituent R2, “optionally substituted... heteroaryl, heteroaryl-lower alkyl and amino” for substituent R3, “halo, cyano, hydroxyl, optionally substituted... lower alkyl, lower alkoxy, lower alkoxy-lower alkyl, aryl, heteroaryl, aryl-lower alkyl, heteroaryl-lower alkyl, alkenyl, alkynyl and amino)” for substituent R5, “cyano, optionally substituted (lower alkyl, lower alkoxy, lower thioalkyl, lower alkenyl, lower alkynyl, lower alkoxy-lower alkyl, aryl, heteroaryl, aryl-lower alkyl, heteroaryl-lower alkyl and amino)” for substituent R6, but does not provide specific structures to limit the claim. Likewise, the substituents of Claim 2 giving rise to the instant rejection are nominally defined by terms such as “optionally substituted ...lower alkenyl and lower alkynyl” for substituent R’1, “optionally substituted... heteroaryl, heteroaryl-lower alkyl and amino” for substituent R’3, “halo or optionally substituted lower alkyl” for substituent R’5, and “optionally substituted (lower alkyl, lower alkenyl, lower alkynyl” for substituent R’6, but does not provide specific structures to limit the claim. Furthermore, while a number of potential variants to the broad classes of subgenera indicated above are proposed as part of the description surrounding the claimed "optional substituted" language, the examiner could identify no compounds within the four corners of the instant disclosure which bear the aforementioned “optional substitutions.” While a great number of particular compounds have been enumerated by the applicants, none which are specifically named or otherwise exemplified possess structural characteristics falling within the genera as outlined above. Accordingly, the claimed subject matter, as particularly outlined above, is not adequately described by the specification as originally filed.

Additionally, the instant claims broadly recite compounds nominally identified by the terms “salt or prodrug ester,” but which do not limit the claimed moieties to a specific structure.

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The only moieties particularly described as potential components of the claimed “salts or prodrug esters” by the instant specification are those set forth at pages 4-5; no others are “specifically named or otherwise exemplified.” Accordingly, the claimed subject matter is not adequately described by the specification as originally filed.

Technological Background Material

4. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Specifically, the species elected by applicants, 4-bromo-2-(4-isopropyl-phenyl)-7-methoxy-1-(2-methoxy-ethyl)-5-(3-methoxy-phenyl)-1H-benzimidazole, as well as the genus described by instant Claim 1 is neither anticipated nor obvious in view of the art discovered by the examiner. While it is true that the art recognizes a variety of benzimidazole compounds, *see, e.g.*, U.S. Patent 5,626,875, U.S. Patent Application Publication 204/0170689, the examiner has concluded that, absent a teaching or motivation to modify the known benzimidazole compounds in such a manner unknown to the examiner at this time, the compounds known in the prior art are sufficiently distinct from those claimed in the instant application to prevent the examiner, in good faith from making out a *prima facie* case of obviousness.

Claim Objections

5. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No Claims are allowable as currently presented. Applicants are advised to contact the examiner at their earliest convenience to schedule a teleconference to discuss allowable subject matter and potential claim amendments which will move the application toward issuance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
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/JEFFREY S. LUNDGREN/

Primary Examiner, Art Unit 1639